

**ANTISEPTIC SKIN CLEANSER- chlorhexidine gluconate 4% liquid**  
**Rite Aid Corporation**

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**4% Rite Aid 8/16oz**

**Active Ingredients**

Chlorhexidine Gluconate 4% Solution

**Purpose**

Antiseptic

**Uses**

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **skin wound and general skin cleansing**

**Warnings**

**For external use only**

**Allergy alert:** This product may cause severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use**

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Stop use and ask a doctor if**

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

**When using this product**

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

**Directions**

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

**Surgical hand scrub:**

- wet hands and forearms with water
- scrub for 3 minutes with about 5 mL of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

**Healthcare personnel handwash:**

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for about 15 seconds
- rinse and dry thoroughly
- repeat procedure for an additional 2 minutes and dry with a sterile towel

**Skin wound and normal skin cleansing:**

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

**Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients**

cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol.

**Questions or comments?**

call **1-800-587-3721** Monday through Friday 8:00 AM to 4:30 PM CST.

**Laundering/Cleaning Instructions:** Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products. Rinse completely and use only non-chlorine detergents.

\*This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.

DISTRIBUTED BY: RITE AID

30 HUNTER LANE,

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ITEM 362278

### **Active ingredient**

Chlorhexidine gluconate 4% solution

### **Purpose**

Antiseptic

### **Uses**

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **skin wound and general skin cleansing**

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- shock
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- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in

this product

- in contact with the meninges
- in the genital area

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### **Keep out of reach of children**

If swallowed, get medical help or contact Poison Control Center right away.

### **Directions**

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

### **Surgical hand scrub:**

- wet hands and forearms under running water
- scrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

### **Healthcare personnel handwash:**

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for about 15 seconds
- rinse and dry thoroughly

### **Skin wound and general skin cleansing:**

- thoroughly rinses the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

**Other information**

- store at 20-25°C (68-77°F)
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**Inactive ingredient**

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**Package label and principal display panel**

Compare to the active ingredient in Hibiclens

NDC 11822-3678-8

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE

4% SOLUTION

dye free

for external use only

TAMPER-EVIDENT:

DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

8 FL OZ (237mL)

▲ Lift Here

Drug Facts	
<b>Active ingredient</b> Chlorhexidine gluconate 4% solution	<b>Purpose</b> Antiseptic
<b>Uses</b>	
<ul style="list-style-type: none"><li>■ surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care</li><li>■ healthcare personnel handwash: helps reduce bacteria that potentially can cause disease</li><li>■ skin wound and general skin cleansing</li></ul>	

**WARNING:** This product can expose you to coconut oil diethanolamine condensate (cocamidopropylamine), which is known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**DISTRIBUTED BY:**  
RITE AID, 30 HUNTER LANE,  
CAMDEN, NJ 08101  
[www.riteaid.com](http://www.riteaid.com)  
**SUBSCRIPTION GUARANTEE:** 0 11822-3678-2  
If you're not satisfied, we'll happily refund your money.

4PA08BTLLBLH



Compare to the active ingredient in **Hibiclens®**

NDC 11822-3678-8

ANTISEPTIC/ANTIMICROBIAL

# SKIN CLEANSER

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4% SOLUTION

dye free  
for external use only



TAMPER-EVIDENT: DO NOT USE IF  
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8 FL OZ (237 mL)

## Drug Facts (continued)

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- in the genital area

#### When using this product

- keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
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### Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- Surgical hand scrub:**
- wet hands and forearms with water
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  - a separate nail cleaner may be used
  - rinse thoroughly
  - wash for an additional 3 minutes with 5 mL of product and rinse under running water
  - dry thoroughly
- Healthcare personnel handwash:**
- wet hands with water
  - dispense about 5 mL of product into cupped hands and wash in a vigorous manner for about 15 seconds
  - rinse and dry thoroughly
  - repeat procedure for an additional 2 minutes and dry with a sterile towel

<p><b>Drug Facts</b> (continued)</p> <p><b>Skin wound and general skin cleansing:</b></p> <ul style="list-style-type: none"> <li>thoroughly rinse the area to be cleaned with water</li> <li>apply the minimum amount of product necessary to cover the skin or wound area and wash gently</li> <li>rinse again thoroughly</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F)</li> <li>avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients</b></p> <p>cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol</p> <p><b>Questions or comments?</b> call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST</p> <p><b>Laundering/Cleaning Instructions:</b> Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.</p> <p><small>* This product is not manufactured or distributed by Mölnlycke Healthcare, owner of the registered trademark Hibiclens®.</small></p>
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## Principal display panel

Compare to the active ingredient in Hibiclens®\*

NDC 11822-3678-7

ANTISEPTIC/ANTIMICROBIAL

SKIN CLEANSER

CHLORHEXIDINE GLUCONATE

4% SOLUTION

dye free

for external use only

TAMPER-EVIDENT: DO NOT USE IF SHRINK SEAL NECKBAND IS BROKEN OR MISSING

16 FL OZ (473 mL)

Compare to the active ingredient in Hibiclens®<sup>®</sup> NDC 11822-0578-7

ANTISEPTIC/ANTIMICROBIAL

# SKIN CLEANSER

CHLORHEXIDINE GLUCONATE  
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DISTRIBUTED BY:

RITE RID, 30 HUNTER LANE,  
CRANFILL, PA 17011 [www.riteaid.com](http://www.riteaid.com)

**SATISFACTION  
GUARANTEE**

If you're not satisfied, we'll  
happily refund your money.



4PA16BTLBLA

## Drug Facts

### Active Ingredient

Chlorhexidine gluconate  
4% solution

### Purpose

Antiseptic

### Uses

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
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- skin wound and general skin cleansing

▲ Lift Here



## Drug Facts (continued)

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# ANTISEPTIC SKIN CLEANSER

chlorhexidine gluconate 4% liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-3678
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3678-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2013	
2	NDC:11822-3678-7	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	01/01/2013	

**Labeler** - Rite Aid Corporation (014578892)

**Registrant** - Xttrium Laboratories, Inc. (007470579)

**Establishment**

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(11822-3678)

Revised: 4/2021

Rite Aid Corporation